105 CMR 162.000: LICENSURE OF SUBSTANCE ABUSE OUTPATIENT SERVICES

Section

Section: continued

SUBPART C - GENERAL REQUIREMENTS

SUBPART D - TREATMENT SERVICES

162.001: Purpose

105 CMR 162.000 sets forth standards for the licensure and operation of substance abuse outpatient services.

162.002: Authority

105 CMR 162.000 is adopted under the authority of M.G.L. c. 111B, § 6B, c. 111E, § 7, and c. 90, §§ 24 and 24d.

162.003: Citation

105 CMR 162.000 shall be known, and may be cited, as 105 CMR 162.000: *Licensure of Substance Abuse Outpatient Services*.

162.004: Scope

105 CMR 162.000 shall govern the licensure and operation of every substance abuse outpatient program subject to licensure under M.G.L. c. 111B, § 6B and c. 111E, § 7, c. 90, §§ 24 and 24d. Substance abuse outpatient programs operating in hospitals are licensed under M.G.L. c. 111, § 51.

162.020: Definitions

The following definitions shall apply for the purpose of 105 CMR 162.000 unless the context or subject matter clearly requires a different interpretation.

Acupuncture Detoxification and Maintenance Program - means an acupuncture treatment program for individuals experiencing the dysfunctional effects of the use of alcohol and/or other drugs and whose primary need is detoxification services for withdrawal and thereafter, time-limited support services for maintenance of sobriety.

Acupuncturist - means an individual licensed by the Board of Registration in Medicine in accordance with M.G.L. c. 112, §§ 148 through 162.

Administrator - means the individual duly appointed by the governing body of the facility who is responsible for the day to day operations of the facility operating the service.

Affiliation Agreement - means a signed and dated document describing the agreed upon terms of a service relationship between the named parties.

Building - means the physical structure in which the service is provided.

Bureau of Substance Abuse Services - means the Bureau of Substance Abuse Services, including its director and staff, of the Department of Public Health.

Case Management for Pregnant and Parenting Women - means those services as defined in 106 CMR 418.000: *Medical Assistance Program: Substance Abuse Treatment Services*.

Client - means a person applying for admission or admitted to the program or service.

Clinician I - means an individual with a minimum of a master's degree in one of the following disciplines or a closely related field: clinical psychology, education-counseling, medicine, psychology, psychiatric nursing, rehabilitative counseling, social work; and a minimum of two years of clinical supervisory experience; and two years of supervised substance abuse counseling experience.

Clinician II - means an individual with a minimum of a master's degree in any of the disciplines mentioned under Clinician I and who has a minimum of one year of supervised substance abuse counseling experience, or has a bachelor's degree in any of the disciplines mentioned in Clinician I and a minimum of three years of supervised substance abuse counseling experience, or has a recognized certification and licensure including 4,000 hours of clinically supervised counseling of substance abuse clients including at least 180 documented hours of counseling and at least 220 documented hours of supervision.

Clinician III - means an individual with a minimum of a high school diploma or equivalent and a minimum of one year supervised counseling experience in substance abuse treatment or a closely related field, who is actively pursuing the requirements of a Clinician II.

Commissioner - means the Commissioner of the Massachusetts Department of Public Health.

Consultation - means the opportunity by which clinicians can present specific client cases to clinicians of equal or greater expertise for the purpose of feedback, direction, and guidance.

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Day Treatment Program - means a treatment program licensed by the Department which provides direct client services a minimum of five days per week through groups, individual, and family substance abuse counseling aimed at supporting abstinence, adaptive behaviors, and the special treatment needs of women, adolescents, and people with HIV/AIDS.

Department - means the Department of Public Health.

Driver Alcohol Education (DAE) Program - means an educational program licensed by the Department and established for individuals adjudicated by a court as first offenders of driving under the influence of intoxicating liquor or controlled substances.

Facility - means a legal entity, whether conducted for charity or profit, established or maintained to provide outpatient substance abuse services.

Full-time equivalent (FTE) means a minimum of 35 hours per week per each staff position.

Intensive Outpatient Treatment Program - means a treatment program licensed by the Department which provides clinical group services to clients a minimum of three days per week presenting factual information about alcohol, drugs, and addiction; incorporates cognitive and behavioral approaches aimed at supporting abstinence and adaptive behaviors; and addresses the special treatment issues of women, adolescents, and people with HIV/AIDS.

Levo-Alpha-Acetyl-Methadol (LAAM) - means the synthetic opiate, or an opioid, which is a longer acting alternative medication to methadone which is used in the maintenance treatment and/or detoxification of opioid dependence.

License - means a license or approval in writing, whether full or provisional, issued pursuant to M.G.L. c. 111B, § 6B, c. 111E, § 7, or c. 90, §§ 24 and 24D.

Licensee - means any facility holding a license from the Department to operate the program or service.

Medication Unit - means a methadone, LAAM, or other narcotic, as defined by state and Federal law, established as part of, but geographically separate from, a narcotic treatment program from which licensed private practitioners and pharmacists are authorized to administer and dispense a narcotic drug and to perform appropriate monitoring for the detection of narcotic drugs. A medication unit must receive its supply of the narcotic drug directly from the stocks of the primary facility.

Methadone - means a synthetic narcotic substance chemically described as 6-dimenthylamino, 4-diphenyl, 3-heptanone. Methadone doses are usually administered as methadone hydrochloride.

Motivational Supportive Counseling - means counseling during the detoxification phase that focuses on engaging the client to remain in acupuncture treatment and during the maintenance phase that motivates the client to transition into a substance abuse outpatient treatment program.

Narcotic Detoxification - means the withdrawal of a client from dependence on heroin or other opiate-like drugs by means of administering or dispensing methadone, LAAM, or other narcotic, as defined by state and Federal law as a narcotic drug, in decreasing dosages in accordance with Federal Food and Drug Administration regulations.

Narcotic Maintenance - means the continued administering or dispensing of methadone or LAAM or other medications defined under M.G.L. c. 94C in conformance with Federal Food and Drug Administration regulations, in conjunction with the provision of appropriate social and medical services, at relatively stable dosage levels as an oral substitute for heroin or other opiate-like drugs, to an individual dependent on heroin or other opiate-like drugs.

162.020: continued

Narcotic Treatment Program - means a treatment program licensed by the Department which furnishes a comprehensive range of assessment, rehabilitation, and treatment services using LAAM, methadone, or other narcotic, as defined by state and Federal law, for the detoxification and/or maintenance of narcotic-dependent persons.

Nurse Practitioner - means an individual licensed by the Board of Registration of Nursing pursuant to M.G.L. c.112, §80B.

Outpatient Detoxification Program - means a facility-based treatment program which does not treat opiod addiction by use of narcotics but which provides detoxification services and counseling by appointment during scheduled operating hours for individuals experiencing the effects of alcohol and other drugs with an emphasis on the provision of medical, counseling, and ancillary treatment.

Pharmacist - means an individual licensed by the Massachusetts Board of Registration in Pharmacy in accordance with M.G.L. c. 112, s§ 4.

Physician - means an individual licensed by the Board of Registration in Medicine pursuant to M.G.L. c. 112, § 2.

Physician Assistant - means an individual licensed by the Board of Registration of Physician Assistants pursuant to M.G.L. c. 112, § 9G.

Pregnant and Parenting Women - means those individuals who meet the definition and eligibility criteria established in 106 CMR 418.000: *Medical Assistance Program: Substance Abuse Treatment Services*.

Primary Facility - means the main premises of a facility licensed to provide outpatient service pursuant to 105 CMR 162.00 *et seq*.

Professional Nurse - means an individual licensed by the Board of Registration in Nursing in accordance with M.G.L. c. 112, §§ 118 through 129, including a registered nurse and licensed practical nurse.

Program - means a specifically licensed treatment component operating under the authority of the substance abuse outpatient service license.

Program Director - means an individual duly authorized by the Governing Body of the facility who is responsible for the day to day operation of a licensed treatment component operating under the authority of the substance abuse outpatient service license.

Program Sponsor - means the licensee, or a person who represents the licensee, who is responsible for the operation of a narcotic treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing services at the program (including its medication units).

Psychiatrist - means a physician licensed by the Board of Registration in Medicine pursuant to M.G.L. c. 112, § 2 and certified by the American Board of Psychiatry and Neurology, or an equivalent body, or eligible for such certification.

Psychologist - means an individual licensed by the Board of Registration of Psychologists pursuant to M.G.L. c.112, §§ 118 through 129.

Public Health Council - means the Public Health Council of the Department of Public Health.

Satellite Office - means a licensed office operating off the main premises of a facility licensed to provide the outpatient substances abuse service which satellite office is open to clients more than 20 hours per week and offers a minimum of 40 staff hours a week of substance abuse treatment services to clients.

162.020: continued

Second Offender Aftercare Program - means a licensed outpatient educational and treatment program established for individuals who have been convicted of a second Driving While Under the Influence (DUIL) offense and who have completed the approved 14 day DUIL second offender residential program.

Service - means a substance abuse outpatient service comprised of one or more programs.

Social Worker - means an individual licensed by the Massachusetts Board of Registration of Social Workers pursuant to M.G.L. c. 112, §§ 130 through 138.

Specialized Substance Abuse Treatment Programs for Pregnant and Parenting Women - means a treatment program which provides Intensive Outpatient Treatment and/or Day Treatment for Pregnant and Parenting Women.

Staff - means an individual, who is an employee designated by the facility to provide the service.

State Authority - means the Department of Public Health.

Substance Abuse Outpatient Counseling - means outpatient rehabilitative treatment for individuals and their families experiencing the effects of the dysfunctional use of alcohol and/or drugs.

Supervision - means a regular and specified time set aside to provide training, education and guidance to clinical staff in the management of their clinical cases. Supervision may be provided one-to-one or in small groups of no more than eight individuals.

Tobacco Free - means an environment free of tobacco use including the use of smokeless tobacco, such as snuff and chewing tobacco.

Transfer of Ownership - transfer of a majority interest in the ownership shall mean: in the case of a corporation, transfer of a majority of stock thereof; in the case of a non-profit corporation, changes in the corporate membership and/or trustees which the Department determines to constitute a shift in control of the facility; in the case of a partnership, transfer of a majority of the partnership interest; and in the case of a trust, change of the trustee or majority of trustees. A transfer of ownership also shall be deemed to have occurred where foreclosure proceedings have been instituted by a mortgagee in possession.

Unmet Need - means the existence of an established waiting list for treatement and/or other statistical data that demonstrates the existence of unmet treatment need.

162.097: Compliance with Federal and State Laws and Regulations

Unless otherwise provided, all substance abuse outpatient services shall be in compliance with the requirements set forth in 105 CMR 162.000 *et seq.*, and shall be in compliance with all Federal, state, and local laws and regulations pertaining to outpatient substance abuse services, including:

(1) FDA regulations;
(2) DEA regulations;
(3) registration with the Department's Division of Food and Drug; and
(4) health and safety requirements.

162.098: Waiver

(A) The Department may waive the applicability of one or more of the requirements imposed on the facility by 105 CMR 162.000 upon finding that:

(1) compliance would cause undue hardship to the facility;

162.098: continued

(2) the facility is in substantial compliance with the spirit of the requirement; and
(3) the facility's non-compliance does not jeopardize the health or safety of its clients and does not limit the facility's capacity to provide the service.

(B) The facility shall provide the Department of Public Health with written documentation supporting its request for a waiver.

162.099: Severability

Any section, subsection, paragraph, sentence, clause, phrase, or word of 105 CMR 162.000 declared to be invalid for any reason shall be severed and shall not affect any other portion of 105 CMR 162.000, which shall remain in full force and effect.

SUBPART A - LICENSING AND OTHER ADMINISTRATIVE PROCEDURES
APPLICATION FOR LICENSURE

162.100: Requirement of Licensure

(1) All outpatient substance abuse services shall file an application for licensure with the Department for the establishment or provision of the service.
(2) Services established and provided by a department, agency, or institution of the Commonwealth shall file an application for approval for the establishment or provision of the service.
(3) Services established and provided by a department, agency, or institution of the Federal government do not require licensure under 105 CMR 162.000.
(4) A licensed hospital offering a separate, identifiable service specifically designed to care for alcohol and/or drug dependent persons requires licensure pursuant M.G.L. c. 111, § 51.

162.101: License Application

(A) Applicants for an initial or renewal license shall submit to the Department an application on an approved form obtained from the Department together with such other documents and materials as the Department shall deem appropriate.

(B) No application shall be accepted unless it is on Department forms, completed in full, and sworn and attested to before a notary.

(C) Fees for the license shall accompany each application and shall be in the amount set by the Department or the Executive Office of Administration and Finance. No fee shall be required when the applicant is the Commonwealth.

162.102: Evaluation of Application

The Department shall not approve an application for an initial or renewal license unless it has determined that there is documented unmet need for addictions treatment at the designated location, has conducted an inspection of the location, and has completed an investigation of the application to determine the applicant's suitability to establish or maintain the service. The evaluation shall include, but not be limited to, a review of the following factors:

(A) The applicant's past performance as a service provider;

(B) The applicant's financial viability;

(C) Any record of criminal activity by the applicant or its employees;

(D) The record of compliance with all applicable Federal, state, and local laws and regulations; and

162.102: continued

(E) Possession of all current local, state, and Federal licenses, approvals, permits, and certificates of inspection.

162.103: Change of Name, Ownership or Location; Non-Transferability of License

(A) The licensee shall notify the Department immediately, and in writing, of any proposed change in location, name, ownership, or control of the facility.

(B) A licensee who intends to change the location of the facility shall submit a completed application for licensure at the new site at least 30 days prior to the intended date of relocation.

(C) Within ten days of a change in ownership or control, the new owner(s) or controlling parties shall file an application for licensure. This application shall have the effect of a provisional license until such time as the Department acts upon the application.

(D) In the case of a transfer of ownership of the facility, the application of the new owner for a license shall not have the effect of a provisional license when the application is not filed within ten days of a change in ownership.

(E) Any notice of hearing, order, or decision which the Department or the Commissioner issues to a facility prior to a transfer of ownership shall be effective against the former owner prior to such transfer and, where appropriate, the new owner following such transfer unless said notice, order, or decision is modified or dismissed by the Department or the Commissioner.

(F) No license shall be transferable from one person to another or from one facility to another.

162.104: Collection and Updating of Information

(A) Each licensee shall submit annual reports in a form approved by the Department on admissions, discharges, client characteristics, and staff patterns and characteristics and file with the Department such data, statistics, schedules, or information as the Department may require for the purposes of licensing and/or monitoring and evaluating a service.

(B) All information submitted under the requirements of 105 CMR 162.000 *et seq.* or otherwise required by the Department shall be kept current by each licensee. Any document which amends, supplements, updates, or otherwise alters a required document must be filed with the Department within 30 days of the change.

(C) Any licensee that fails to furnish such data, statistics, schedules or information as the Department may require, or who files fraudulent returns thereof, shall be punished by a fine of not more than $100 pursuant to M.G.L. c. 111B, § 6B.

162.110: Inspection

(A) Each applicant or licensee shall be subject to visitation and inspection by the Department at any time:

(1) prior to the granting or renewing of a license; and
(2) for the purpose of monitoring and evaluation.

(B) Refusal to allow entry to the Department shall constitute grounds to seek a complaint for a warrant in district or superior court to authorize entry, pursuant to M.G.L. c. 111E, § 7.

(C) Refusal to allow entry to the Department shall constitute adequate and independent grounds for license or approval denial, suspension, revocation, and/or refusal to renew.

162.111: Deficiency Corrections Orders

After every inspection in which any violation of 105 CMR 162.000 is observed, the Department shall prepare a written deficiency correction order citing every violation observed; a copy of which shall be sent to the licensee. The deficiency correction order shall include a statement of the deficiencies found, the period within which the deficiency must be corrected, and the provision(s) of law and regulation relied upon. The period shall be reasonable and not less than 30 days from receipt of the correction order, unless the Department determines that swifter correction is necessary for client health and safety.

162.112: Plan of Correction

(A) The licensee shall submit to the Department a written plan of correction for violations cited in a deficiency correction order within ten business days after the deficiency statement is sent.

(B) The plan of correction shall set forth, with respect to each deficiency, the specific corective step(s) to be taken, a timetable for such steps, and the date by which full compliance will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. The plan of correction shall be signed by either the applicant or licensee or his/her designee.

(C) The Department shall review the plan of correction and will notify the licensee of either the acceptance or rejection of the plan. An unacceptable plan must be amended and resubmitted within ten business days of the date of notice of rejection.

162.120: Renewal of License

(A) The Department shall send each licensee notification of the need to renew its license and the necessary application forms no later than 90 days prior to the expiration of an existing license.

(B) The licensee shall complete and return the application form 60 days prior to license expiration date, together with other information and materials that the Department may deem appropriate.

(C) When a licensee submits a timely application for a renewal license, its previous license shall be valid until the Department acts on its renewal application.

162.121: Period of License

The term of the license shall be for two years from the date of issue, and any renewals thereof shall be for two years, unless otherwise provided.

162.122: Provisional Licenses

(A) All new applicants who have not been previously licensed to provide the services as defined in 105 CMR 162.020 shall be issued a provisional license.

(B) When the Department finds that an applicant for re-licensure has not complied with all applicable regulations, but is in substantial compliance and has submitted an acceptable plan of correction for bringing the facility into full compliance, the Department may issue a provisional license, provided that the service offered is adequate to protect the health and safety of the clients.

(C) A provisional license is valid for a period not to exceed six months and may be renewed once for no more than six months. The Department shall issue a provisional license only when an applicant submits a written plan for full compliance. This written plan shall include specific target dates for accomplishing full compliance.

162.123: Posting of License

Each licensee shall post in a conspicuous place at each service location the current license issued by the Department.

162.130: Legal Proceedings

Every licensee shall report in writing to the Department any criminal or civil action that is brought against the licensee or any person employed by the licensee which relates to the delivery of the service or which may impact on the continued operation of the facility. The report shall be given to the Department within ten days of initiation of such action.

162.131: Notification of Death, Serious Incident, Accident, or Fire

(A) The licensee shall notify the Department orally as soon as possible, and in writing within 72 hours of knowledge of a client or staff death where death occurs on site or in treatment-related circumstances. Where appropriate, the licensee shall notify the decedent's family or next-of-kin.

(B) The licensee shall notify the Department, as soon as possible, and in writing within 72 hours of any serious accident requiring medical attention involving a client or staff occurring on the premises and/or related to the operation of the service.

(C) The licensee shall notify the Department, as soon as possible, and in writing within 72 hours of any fire or accident resulting in damage to the building.

162.132: Closure

(A) When a licensee plans to cease operation of a service or program or ceases to operate a service through license denial, denial of a renewal, suspension, revocation, or when the licensee voluntarily closes a service or program, the licensee shall be responsible for:

(1) in the case of voluntary closure, notifying the Department in writing at least 21 days prior to cessation of operations and closure. For the purposes of 105 CMR 162.000, voluntary closure shall include foreclosure or bankruptcy proceedings;

(2) orally notifying each client at least 21 days prior to the termination of service or program that the service or program will cease;

(3) developing a written referral plan in collaboration with each client that will include a plan for continuing the client's service if appropriate; and

(4) assuring that clinical records are securely stored or accompany clients upon transfer. Transfer and storage of records will be made in accordance with Federal and state confidentiality law and regulations. A signed release from each client shall be obtained prior to the transfer of such records.

(B) The Department may, in exceptional circumstances, grant permission for the temporary closure of the service for a period no longer than 30 days when the Department finds that clients will not be affected adversely by the temporary closure.

162.140: Grounds for Suspension of License

The Department may summarily suspend a license if the continued operation of the program or service poses an immediate threat to the health or safety of its clients. The licensee may not operate during the period of suspension of its license, after notification of the suspension.

162.141: Grounds for Denial, Refusal to Renew, Restriction, Limitation, or Revocation of License

Each of the following, in and of itself, shall constitute full and adequate grounds to deny, revoke, limit, restrict, or refuse renewal of a license:

(A) Lack of capacity or suitability to provide the service covered by a license as determined pursuant to 105 CMR 162.102;

(B) Failure to submit the required license fee;

162.141: continued

(C) Failure to meet the requirements of applicable Federal, state, or local laws or regulations;

(D) Failure to give proper patient care to clients;

(E) Failure to meet the requirements for licensure as specified in 105 CMR 162.000, including but not limited to:

(1) Failure to submit an acceptable plan of correction pursuant to 105 CMR 162.112; or

(2) Failure to remedy or correct a cited violation by the date specified in the plan of correction as accepted or modified by the Department;

(F) Denial of entry to agents of the Department or attempt to impede the work of a duly authorized representative of the Department;

(G) Providing false or misleading statements to the Department;

(H) A facility owned or operated by the applicant or licensee has been the subject of proceedings which resulted in the suspension, denial, modification, limitation, or revocation of license or refusal to renew the license;

(I) A facility owned or operated by the applicant or licensee has been the subject of proceedings which were ultimately resolved by settlement agreement but which were initiated to suspend, deny, modify, limit, or revoke or refuse to renew the license;

(K) The applicant or licensee has been disciplined in another jurisdiction in any way by a licensing authority for reasons substantially the same as those set forth herein;

(L) The applicant or licensee operated the facility after the expiration of a license;

(M) If there is a reasonable basis for the Department to conclude that there is a discrepancy between the representations by a facility as to the treatment services to be afforded patients and the treatment services actually rendered or to be rendered; and/or

(N) Other grounds: Nothing herein shall limit the Department's adoption of policies and grounds for denial, refusal to renew, or revocation through adjudication, as well as through rule making.

162.142(A): Hearings: Procedure

(A) Suspension of a License.

(1) Upon suspension of a license, the Department shall give the licensee written notice thereof, stating the reason(s) for the suspension and the provisions of law relied upon. The suspension shall take effect immediately upon issuance of the notice.

(2) Upon written request, the licensee shall be afforded an opportunity to be heard concerning the suspension of the license by the Department.

(3) If the applicant or licensee requests a hearing, the Department shall initiate an adjudicatory hearing pursuant to 801 CMR 1.00 *et seq*. no later than 21 calendar days after the date of the suspension.

(4) The hearing officer shall determine whether the Department has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the suspension, an immediate threat to the health and safety of the licensee's clients.

162.142(B): Denial, Restriction, Limitation, Revocation, or Refusal to Renew a License

(A) If the Department determines that a license should be denied, restricted, limited, revoked, or refused renewal, the Department shall provide written notice to the applicant or licensee of:

(1) the intended action;

(2) the reasons and grounds therefore; and

(3) the applicant's or licensee's right to file a written request for an adjudicatory hearing in accordance with M.G.L. c. 30A and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 *et. seq*.

162.142B: continued

(B) Upon receipt of Notice of Claim for an Adjudicatory Proceeding, the Department shall initiate a hearing pursuant to 80l CMR 1.01 *et. seq.*

(C) The hearing officer shall determine whether the Department has proved by a preponderance of evidence that the license should be denied, restricted, limited, revoked, or refused renewal based upon relevant facts as they existed at or prior to the time that the Department initiated the action.

(D) If the hearing officer finds any single ground for denial, restriction, limitation, revocation, suspension, or refusal to renew a license, the hearing officer shall render a recommended decision affirming the decision of the Department.

162.144: Public Health Council and Judicial Review

(A) The recommended decision of the hearing officer in any adjudicatory proceeding conducted pursuant to 105 CMR 162.142 shall be reviewed by the Commissioner and the Public Health Council. After review, their decision shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

(B) A licensee or applicant that fails to exercise the right to an adjudicatory proceeding pursuant to 105 CMR 162.142 waives both the right to administrative review by the Commissioner and the Public Health Council and the right to judicial review pursuant to M.G.L. c. 30A, § 14.

162.200: General Requirements

Licensees shall comply with all Federal and state laws and local ordinances applicable to buildings, zoning, fire protection, public safety and public health, and accessibility.

162.201: Inspections

(A) The licensee shall have and post conspicuously a current and valid certification of inspection from the Department of Public Safety or the appropriate local building inspector. Said certification shall remain current and valid throughout the period of licensure.

(B) The licensee shall request from the local fire department annual fire inspections in each building, the result of which shall be kept and maintained in the licensee's files. Said certification shall remain current and valid throughout the period of licensure.

162.202: Heating

(A) Each building shall be equipped with a heating system that is sufficient to maintain a minimum temperature of 68°F throughout the building during cold weather. Portable heaters using kerosene, gas, or other open-flame methods are prohibited.

(B) The heating system shall be in conformity with the rules and regulations as outlined by the Department of Public Safety (520 CMR, 522 CMR, and 527 CMR) under M.G.L. c. 148, as amended.

(C) Plumbing and heating shall be adequate to maintain a comfortable and healthy environment for clients. Hot water supplied to fixtures accessible to clients shall be controlled to provide a maximum temperature of 110°F.

162.203: Lighting

Adequate electric lighting, maintained in good repair, shall be provided throughout the building and at the recommended levels of the Illumination Engineering Society. All electrical installations shall be in accordance with the Department of Public Safety (520 CMR), Board of Fire Prevention Regulations (527 CMR), Massachusetts Electrical Code (527 CMR), and all local regulations.

162.204: Building Design

(A) The design, construction, and furnishings of the building shall comply with all Federal and state laws and local ordinances pursuant to 105 CMR 162.223.

(B) Each site proposed for the delivery of the service shall require the prior written approval of the Department. Written approval shall also be required for any change in location of an existing service.

(C) Applicants for first-time licensure or licensees that relocate shall locate programs and/or services in accessible facilities. Failure of an applicant to so locate shall be grounds for denial of licensure.

162.210: Building Maintenance

(A) All licensees shall provide sufficient maintenance personnel and housekeeping to insure that the building is in good repair and in a safe, clean, and sanitary condition and free from accumulation of refuse.

(B) Each building shall have adequate space for storage of equipment and bulk office supplies and all storage areas, attics, and cellars shall be kept safe and free from accumulations of refuse. Combustibles, whose storage is permissible under relevant state and local regulations, shall be kept in metal cabinets.

(C) All doorways, corridors, and stairwells shall be maintained so as to provide free and unobstructed egress from all parts of the building:

(1) an emergency source of lighting shall be available in all corridors and stairways that lead to the principal means of egress;
(2) all stairways shall be equipped with handrails; and
(3) areas around the buildings, sidewalks, and patios shall be kept clear of ice and snow.

162.220: First Aid Supplies

The licensee shall keep first aid supplies in a convenient and safe place ready to be used for minor injuries.

162.221: Basic Life Support

During the hours that the service is provided, there shall be a minimum of one staff person on site who is trained and certified in Cardio Pulmonary Resuscitation (CPR).

162.222: Emergency Plans

(A) The licensee shall establish a written plan detailing procedures for meeting potential emergencies. The emergency plan shall include:

(1) procedures for the emergency evacuation of infants, children, and persons with disabilities on the premises;
(2) procedures for the assignment of personnel to specific tasks and responsibilities in emergency situations;
(3) instructions relating to the use of alarm systems and signals;
(4) procedures for notifying appropriate persons; and
(5) specification of evacuation routes and procedures.

(B) The licensee shall post the plans and procedures at suitable locations throughout the building. The licensee shall familiarize staff and clients with these plans and procedures.

(C) The licensee shall conduct and document emergency evacuation drills semi-annually.

162.223: Services for People with Disabilities

(A) The applicant/licensee shall comply with the policy of the Bureau of Substance Abuse Services on access for individuals with disabilities.

162.223: continued

(B) The licensee shall ensure that all its program(s) or services comply with all applicable Federal, state, and local laws, regulations, and ordinances regarding nondiscrimination for individuals with disabilities.

162.224: Fire Protection

Each applicant/licensee shall provide adequate fire protection equipment and devices appropriate to the needs of the particular building. During the periodic inspection required under 105 CMR 162.201, the licensee shall consult with the local fire department regarding the selection of devices, such as fire alarms and fire extinguishers, and will provide those devices recommended in the inspection report in a timely manner.

162.225: Child Safety Protection

The licensee which offers treatment services or child care services for children, shall ensure that its building or premises are safe for children and that children on site are supervised at all times. At a minimum, where children have access, there shall be:

(A) Covers on electrical outlets;

(B) Gates on stairways;

(C) Banisters and balusters intact; and

(D) No dangerous protruding objects from floors or walls.

162.226: Tobacco-Free Environment

(A) The licensee shall establish written policies that ensure that the service site is tobacco-free by July 1, 1996.

(B) Tobacco use must be prohibited throughout the entire facility with no exceptions, including all indoor facilities, offices, hallways, waiting rooms, restrooms, elevators, meeting rooms, and community areas. This policy applies to all employees, clients, consumers, contractors, and visitors.

(C) Such policies shall ensure that a tobacco cessation program is available, either on site or through referral, for both clients and staff within six months of licensure.

162.230: General Areas

(A) Each building shall have sufficient and separate space for reception and office areas, including:
(1) reception and waiting areas;
(2) administrative and staff offices; and
(3) storage of client records.

(B) Client records shall be kept in secure and locked files accessible only to authorized staff.
(C) Program service areas shall be designed and furnished in a manner consistent with their use and so as to safeguard client dignity and privacy.

162.231: Restrooms

(A) Restrooms shall be conveniently located and accessible throughout the building.

(B) Restrooms shall be designed so that in an emergency the locked door can be opened from the outside.

162.231: continued

(C) Restrooms shall be designed to ensure privacy with the use of partitions and doors.

(D) Restrooms shall have adequate ventilation devices.

(E) Restrooms shall be in good repair, cleaned frequently, and maintained in a sanitary manner.

(F) Restrooms shall have sufficient supplies, *e.g.* soap,paper towels, and toilet tissue, at all times.

162.300: Organization

(A) The licensee shall have a governing body that is accountable for and has authority over the policies and activities of the service and which is representative, at least in significant part, of the community it serves. Minutes and records of meetings shall be documented in accordance with the licensee's by-laws. The licensee shall document that the program director has reported to the governing body or its designated representative at least four times per year.

(B) The ownership and governing body shall be fully disclosed to the Department, including the names and addresses of all owners, officers, directors, controlling persons, and financial investors whether they be individuals, general and/or limited partnerships, corporate bodies, or subdivisions of other bodies.

(C) The licensee shall keep, maintain, and make available to any employee or client an organizational chart and written policy that describes the organizational structure including lines of authority, responsibility, communication, and staff assignment.

(D) The licensee shall appoint a qualified administrator to be responsible for the day-to-day operations of the facility. The administrator shall be on the premises during the workday. In his/her absence a professional staff person shall be designated to act in his/her place.

(E) Each licensee shall establish a system of business management and staffing to assure that the facility maintains complete and accurate accounts, books, and records, including required financial, personnel, and client records.

162.301: Goals and Objectives

(A) Each licensee shall adopt and maintain a current written statement of purpose identifying service goals, objectives, and philosophy. This statement shall be reviewed annually and modified as necessary, reflecting changes in the characteristics of the clients served, changes within the community where the service is located, or recommended changes as a result of a facility evaluation. This statement shall also be maintained in the client policy manual as outlined in 105 CMR 162.306(A)(1).

(B) The licensee shall have an evaluation plan that will enable it to measure the progress being made in reaching its stated goals and objectives. The evaluation plan shall be prepared annually by the licensee and reviewed with the governing body. This plan shall address methods for reviewing appropriateness of client care, utilization of service components, methods for achieving compliance with the Federal and state disability laws, and other data and information that would be useful in improving the provision of the services.

(C) The evaluation plan shall establish and maintain a quality assurance system which contains the following components:

(1) an evaluation which measures the service performance against the criteria set by the licensee in the annual plan;

(2) a utilization review system which analyzes the licensee's policies and practices in admissions, readmissions, length of stay, and criteria for denying admission;

(3) requirements for periodic client-care monitoring which examine selected individual client care and services; and

(4) a system that maintains a format for the collection, review, and consideration of client feedback.

162.301: continued

(D) The evaluation plan shall measure the levels and types of services delivered and the performance of the program over the past year; and it shall identify and articulate areas for program development during the upcoming year. It shall be completed for the following required services:

(1) outreach services;
(2) intake services;
(3) assessment services;
(4) treatment planning;
(5) counseling and other treatment services;
(6) discharge and aftercare planning;
(7) emergency services; and
(8) referral or consultation services.

(E) The licensee shall designate the individual(s) responsible for completing the evaluation plan.

(F) The program shall conduct client-care monitoring activities which include the review of a sample of treatment and other services provided to identify opportunities for improvement of treatment services. Client-care monitoring shall include, at minimum, a review of the following:

(1) unresolved diagnoses;
(2) unimproved clients;
(3) treatment complications;
(4) use of special treatment procedures;
(5) medication usage;
(6) client care incidents or emergencies; and
(7) accessibility for the disabled.

162.302: Finances

(A) The applicant or licensee shall demonstrate financial capability to operate the facility for the licensing period. The licensee shall annually, on or before the 15th day of the fifth month after the end of its fiscal year, document a complete Independent Auditor's Report, including a management letter.

(B) The licensee shall keep and maintain in accordance with state requirements and its by-laws an accurate record of the finances of the facility.

(C) The licensee shall keep on file an annual operating budget with documentation of governing body approval. Such budget shall categorize revenues by source of funds and expenses by service components and shall include a variance report.

(D) The licensee shall establish written procedures and policies for all fiscal operations, including policies and procedures for fee arrangements with clients. In the event of client non-payment, the licensee shall, at minimum, prior to moving to discharge of the client:

(1) make reasonable efforts to secure payment from a third-party payment source; and
(2) offer a reasonable payment plan which takes into account the client's income, resources, and dependents.

(E) Each licensee shall have general and professional liability insurance.

162.303: Client Records

(A) The licensee shall maintain a distinct substance abuse section within the client’s general medical record.

(B) The written individual client record shall include, but not be limited to, the following information:

(1) name, Bureau Management Information System client identifiers, date of birth, sex, race/ethnicity, relationship status, and primary language, if other than English;

162.303: continued

(2) a complete initial diagnostic evaluation that includes: social, economic, and family histories, educational and vocational achievements, criminal history, medical history, and drug/alcohol use and treatment history for clients receiving substance abuse outpatient counseling services;
(3) an assessment completed on a standardized instrument approved by the Bureau for clients receiving driver alcohol education services;
(4) the referring agency, courts, or person;
(5) sources of financial support;
(6) presenting problem(s);
(7) signed and dated progress notes by the client's counselor entered after every client contact or attempted contact;
(8) an original service plan and service plan reviews;
(9) a discharge summary;
(10) aftercare service plan;
(11) attempts at follow-up by letter, phone call, home visit or through contacts with aftercare providers, as appropriate and with the written consent of the client, no more that 30 days subsequent to termination;
(12) all necessary authorizations and consents; and
(13) evidence of a recommendation for treatment (not required for DAE clients).

(C) Acupuncture client records need only contain items 106 CMR 162.303(B)(1), (5), (6), (8), (9), (10), (12), and (13).

(D) Progress notes shall be current, legible, dated, and signed by the individual making the entry. Group counseling and educational-session progress notes may describe the session in general, but the client's record must also include in each progress note specific comments on the client's participation and progress in the group.

(E) All cases of a Clinician II and III shall receive a quarterly record review by his/her supervisor. Evidence of this review shall appear in the clinical record.

(F) All client records shall be marked confidential and kept in a secure, locked location.

(G) Except as otherwise provided in 105 CMR 162.304 or by applicable state or Federal law, access to client records shall be limited to the client or his\her designee and to those staff members authorized by the administrator. The licensee shall have a written procedure regulating and controlling access to client records by staff members whose responsibilities require that they have access.

(H) The licensee shall not develop any procedure prohibiting Department personnel access to client records for the purpose of review authorized by law.

(I) Transfer and/or Storage of Service Records.
(1) The licensee shall maintain client records in a secure place for seven years from the date of the client's termination of services.
(2) In the event of a facility closing, client records may be transferred to another licensed service provider consistent with the client's written consent for the transfer of such records.
(3) Where a service closes and clients are not referred, the facility shall be responsible for the secure storage of such records. Public notice shall be given regarding the date of service termination and the site at which such records shall be secured. The records shall be sealed and retained for seven years from the date of the program's closure. At the end of seven years the records shall be destroyed.

162.304: Confidentiality

(A) Client-specific information shall be privileged and confidential and shall be made available only in conformity with all applicable state and Federal laws and regulations regarding the confidentiality of client records, including but not limited to, 42 CFR Part 2, as amended.

162.304: continued

(B) Client-specific information, whether written or unwritten, shall be made available only where authorized by the prior informed consent of the client. Client consent is required for release of confidential client-specific information, unless one of the following exceptions applies:

(1) to medical personnel in a medical emergency;

(2) to qualified personnel for the purpose of conducting scientific research, management audits, or program evaluations, and then only if all client identifying data is removed; or

(3) if authorized by an order of a court of competent jurisdiction in accordance with 42 CFR Part 2.

(C) A client's informed consent for the release of information shall be in writing and shall contain:

(1) the specific name or general designation of the program or person permitted to make the disclosure;

(2) the name or title of the individual or the name of the organization to which disclosure is to be made;

(3) the name of the client;

(4) the purpose of the disclosure;

(5) how much and what kind of information is to be disclosed;

(6) the signature of the client and, when required for a client who is a minor, the signature of a person authorized to give consent, or, when required for a client who is incompetent or deceased, the signature of a person authorized to sign in lieu of the client;

(7) the date on which the consent is signed;

(8) a statement that the consent is subject to revocation at any time, except to the extent that the program or person which is to make the disclosure has already acted in reliance on it; and

(9) the date, event, or condition upon which the consent will expire if not previously revoked. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(D) Any disclosure made, whether it be with or without the client's consent, shall be limited to information necessary in light of the need and purpose for the disclosure.

(E) Unless requested by the client only the administrator or his/her designee shall release information from client records.

(F) A request for release of information by a client shall not be denied.

(G) All present or past staff members who have access to, knowledge of, or possess any information pertaining to present or former clients shall be governed by 105 CMR 162.000.

(H) The licensee shall, as part of its orientation, notify all staff members and clients, in writing, of these confidentiality requirements. Evidence of this notification shall appear in both personnel and clinical records.

(I) The licensee shall have written policies and procedures controlling access to records and information pertaining to HIV/AIDS and HIV/AIDS testing pursuant to M.G.L. c. 111, § 70F.

162.305: Client Rights

(A) The licensee shall make every effort to safeguard the legal and civil rights of each client at all times regarding the Treatment process and Discharge from Treatment process. Each licensee shall adopt and maintain a currently updated set of facility rules which shall state the responsibilities and the rights of clients regarding the Treatment process and Discharge from Treatment process.

(B) Specific Client Rights. At a minimum, the licensee shall guarantee the client:

(1) freedom from physical and psychological abuse;

(2) freedom from strip searches and body cavity searches;

(3) control over his/her bodily appearance;

162.305: continued

(4) access to his/her client record in the presence of the administrator or designee;
(5) the right to challenge information in his/her client record by inserting a statement of clarification or letter of correction signed by both the clinician and the client;
(6) the right to terminate treatment at any time;
(7) freedom from signing over his/her public assistance, food stamps, or other income to the licensee, except when it is part of a mutual treatment agreement signed by both the client and the licensee;
(8) treatment without invideous regard to race, ethnicity, creed, national origin, religion, sex, sexual orientation, age, or disability;
(9) treatment in a manner sensitive to individual needs and which promotes dignity and self-respect;
(10) full disclosure regarding fees charged; and
(11) receipt of a copy of client grievance procedures upon request.

(C) The licensee rules shall also include written grievance procedures for the resolution of any client-related problem or dispute which arises within the program. The procedures shall provide that, if the matter is not settled to the satisfaction of the client, the client is entitled to a hearing presided over by an impartial grievance officer. The grievance officer selected by the Provider shall be selected based on the issue being grieved (medical officer\medical grievance, administrative officer\administrative grievance). The grievance procedures shall include the process by which clients have the right to grieve:
(1) clinical decisions affecting their treatment; and
(2) any incident or condition that the client believes violated his/her rights.

162.306: Client Policy Manual

(A) Each licensee shall adopt and maintain a current policy manual containing clear and concise statements regarding:
(1) Program goals and objectives, types of services provided, the specific qualifications for service delivery staff, restrictive criteria for receipt of specific services, if any, scheduling restrictions, and overall hours of program operation;
(2) Admission requirements and intake procedures, including a statement that the minimum information to be collected at the intake session shall include social, economic, and family histories, educational and vocational achievement, criminal history, and medical, drug, and drug-treatment histories;
(3) Fee policies and reduced fees for persons of low income, including a statement indicating whether or not the program accepts public or private third-party reimbursement or funding;
(4) Procedures regulating access to client records; and
(5) Program rules, including:
(a) all obligations imposed on clients and the sanctions for their violation;
(b) criteria for termination;
(c) procedures for involuntary terminations;
(d) grievance procedure for the resolution of any other client related problem or dispute;
(e) client rights pursuant to 105 CMR 162.305; and
(f) the client's right to contact the Bureau.
(6) Policies, practices, and procedures for the disabled.

(B) The policy manual shall be made available to all clients and/or interested parties in the following ways:
(1) available in an area frequented by all clients or kept in a central location, with a notice of its placement conspicuously posted in an area frequented by all clients; and
(2) given to each new client during the admission process or subsequently upon their request, and to any interested party upon request.

(C) When furnishing a client with a copy of the policy manual, or any change thereto, the licensee shall secure a dated and signed receipt which shall be placed in the client record.

162.306: continued

(D) Whenever the licensee makes a change in policy, it shall issue a written change to the policy manual; such change shall not take effect until placed and distributed as provided for the manual itself in 105 CMR 162.306(B).

(E) The licensee may charge a reasonable fee for the cost of copying and assembling when giving a copy of the policy manual to an interested party or a second copy to a client.

162.310: Personnel Policies

(A) Each licensee shall describe, in writing, the facility's current personnel policies and practices and shall make them available to all staff members.

(B) Such personnel policies shall include a description of:

(1) the criteria and procedures for hiring, assigning, promoting, and suspending or dismissing a staff member;

(2) the procedure for handling staff complaints and grievances;

(3) provisions for vacations, holidays, paternity and maternity leave, educational leave, sick leave, and other leaves of absence, and fringe benefits;

(4) staff member accident and safety procedures;

(5) policies and procedures regarding sexual harassment; and

(6) nicotine use/smoking policies.

162.311: Job Descriptions and Evaluations

(A) The licensee shall make available job descriptions of all positions, and these shall include current salary ranges.

(B) The licensee shall evaluate the job performance of all staff members. Such evaluation shall be done at least annually, and a copy shall be placed in the employee's record.

(C) Job descriptions shall specify responsibilities, degree of authority to execute job responsibilities, standards of job performance related to the specified job responsibilities, and qualifications.

162.312: Personnel Records

(A) The licensee shall maintain a personnel record for each employee.

(B) Such records shall be kept confidential and at a minimum contain:

(1) a copy of the employee's application for employment or resume;

(2) evidence that the employee is currently certified, licensed, or registered where applicable laws and/or regulations require certification, licensure, or registration;

(3) evidence of training received in:

(a) client confidentiality;

(b) communicable diseases, including HIV, TB, and hepatitis; and

(c) facility policies and procedures.

(4) documentation of current cardiopulmonary resuscitation (CPR) certification;

(5) documentation of an annual TB test;

(6) background information reviews with the Criminal History Information Board, where required; and

(7) annual performance evaluations.

162.313: Training

(A) The licensee shall provide ongoing staff training and supervision appropriate to the size and nature of the facility and staff involved.

(B) The licensee shall have a written plan for the professional growth and development of all personnel. At a minimum, this plan shall include monthly scheduled in-service training which include:

162.313: continued

(1) orientation to program policies and procedures;
(2) state and Federal confidentiality regulations;
(3) clinical assessment and diagnosis;
(4) treatment planning;
(5) relapse prevention;
(6) record keeping;
(7) case management;
(8) aftercare planning;
(9) dual diagnosis; and
(10) HIV/AIDS: licensees shall utilize a training model for HIV/AIDS that develops staff skills to provide direct client education in either an individual or group setting. HIV/AIDS training shall include, but need not be limited to, the following:
(a) the etiology and transmission of HIV infection and associated risk behaviors;
(b) symptomatology and clinical progression of HIV infection and AIDS;
(c) prevention of transmission, or risk reduction;
(d) the purpose, uses, and meaning of available testing and test results;
(e) confidentiality issues; and
(f) the interaction between alcohol and other drug use and its effect on the immune system and the progression of AIDS.

(C) The licensee shall document in the personnel record that each medical and clinical staff member, working directly with clients, receives at least 16 hours of certified and credentialed continuing education annually in addition to the regularly scheduled in-service trainings.

162.314: Volunteers/Student Interns

Volunteers and student interns may be used only as an adjunct to regular paid staff and not as a substitute for a paid work force. Student interns and volunteers providing individual and/or group counseling shall be screened, oriented, trained, and supervised in a manner consistent with 105 CMR 162.000. A training/education plan and quarterly performance reviews shall be documented in the personnel record.

162.320: Staffing Pattern

The licensee shall provide an adequate number of qualified personnel to fulfill the service objectives and to satisfy the intent of 105 CMR 162.000.

162.321: Multidisciplinary Team

(A) In order to meet client needs a multidisciplinary team shall include professionals with a variety of recognized expertise in substance abuse treatment. The team may include physicians, psychiatrists, psychologists, acupuncturists, nurse practitioners, physician assistants, registered nurses, social workers, psychiatric nurses, substance abuse counselors with master's or bachelor's degrees in a related field and certified substance abuse counselors.

(B) The licensee shall ensure that clients have access to this expertise on-site or on an on-call basis to the extent required to meet their needs. A written staffing plan shall be established to ensure this requirement.

(C) Cases presenting unique issues or of special educational value to staff shall be presented to the multidisciplinary team for consideration. A summary of the multidisciplinary case conference must be included in the client record.

162.322: Minimum Staffing Requirements

(A) The staff of each outpatient substance abuse service must include a minimum of one full-time Clinician I responsible for the clinical/educational operation of the substance abuse service.

162.322: continued

(B) The licensee shall have, either on staff or through an annually renewed affiliation agreement, the services of a licensed physician, psychiatrist, psychologist, registered nurse, nurse practitioner, or physician assistant.

(C) Licensees providing narcotic treatment services or services for children and adolescents shall conduct and document in the personnel record background information reviews on all new clinical and medical staff with the Criminal History Information Board.

(D) Staff providing services for children and adolescents shall have specific training in child and teen development, including a minimum of five college credit hours in courses related to the topic.

(E) There shall be additional minimum staffing requirements for the following specialized programs:

(1) Acupuncture. Licensees operating an acupuncture program shall have on staff and onsite during the hours of operation:

(a) an acupuncturist;

(b) at minimum, a Clinician II to provide motivational counseling; and

(c) a physician assistant, nurse practitioner, or registered nurse shall be on staff for the purpose of conducting the medical screening.

(2) Day Treatment. Licensees operating a day treatment program shall have a minimum of one full-time Clinician I on staff and onsite. Additional full-time clinical staff (Clinician I or II) shall be required based on a client to clinical counseling staff ratio of 8:1. Full-time equivalencies may be used only for such time as is necessary to achieve the 8:1 ratio.

(3) Intensive Outpatient. Staff providing services in an intensive outpatient treatment program must be either a Clinician I or a Clinician II.

(4) Second Offender Aftercare Program. A licensee operating a second offender aftercare program shall employ, at minimum, one Clinician II with work experience in a first or second offender operating under the influence program.

(5) Narcotic Treatment Program. The licensee shall designate a physician as Medical Director who shall be responsible for administering all medical services performed by the program and have six months clinical experience with narcotic-dependant persons or ten hours of documented continuing education credit in treating narcotic-dependent persons within the first six months of employment.

(6) Outpatient Detoxification Program.

(a) The licensee shall designate a physician as Medical Director who shall be responsible for administering all medical services performed by the program and have six months clinical experience with alcohol and other drug-dependent persons or 40 hours of documented continuing education credit in treating addicted persons within the first six months of employment.

(b) One physician assistant, nurse practitioner, or registered nurse shall be on staff and onsite during hours of operation of the service.

(c) The ratio of client to clinical counseling staff ratio shall not exceed 8:1.

(7) Driver Alcohol Education. Group education sessions shall be conducted by either a Clinician I or II.

162.323: Consultation and Supervision of Clinical and Medical Staff

(A) A Clinician I shall receive a minimum of one hour of individual or group consultation every week from another Clinician I.

(B) A Clinician II shall receive a minimum of one hour of individual or group supervision from a Clinician I every week and an additional minimum of one hour per month if he/she is responsible for supervising other staff.

(C) A Clinician III shall receive four hours of individual supervision and an additional two hours of individual or group supervision per month from a Clinician I or II.

(D) Staff who are not full-time employees of the service shall receive supervision in proportion to the number of hours worked, with a minimum of one hour of supervision per month.

162.323: continued

(E) A schedule of supervision shall be available for review.

(F) Consultation to staff shall be available from a fully qualified physician or psychiatrist, either on-site or through an affiliation agreement. If services are to be available through an affiliation agreement, this agreement shall be reaffirmed yearly.

162.400: Hours of Operation by Program

(A) Substance Abuse Outpatient Counseling. The program shall be open to provide services 40 hours per week, of which seven hours shall be at a time other than the regular 9:00 A.M. to 5:00 P.M., Monday through Friday schedule. A satellite office shall be open to clients more than 20 hours a week and, on a regular basis, offer more than 40 staff hours a week of substance abuse services to clients.

(B) Acupuncture. Acupuncture programs shall be open to provide services a minimum of six days per week, 52 weeks per year. Daytime hours shall include morning services and ensure maximum accessibility to clients without an appointment. Hours shall include seven hours which shall be at a time other than the regular 9:00 A.M. to 5:00 P.M., Monday through Friday schedule.

(C) Day Treatment. Day Treatment programs shall be open to provide services a minimum of five days per week, four hours per day.

(D) Intensive Outpatient. Intensive outpatient treatment programs shall be open to provide services a sufficient number of hours so that services may be provided a minimum of three days per week.

(E) First Offender Driver Alcohol Education (DAE). Approved programs shall administer 40 hours of counseling service over a period of 16-20 weeks.

(F) Second Offender Aftercare. The program shall be open to provide servcies a minimum of seven hours which shall be at a time other than the regular 9:00 A.M. to 5:00 P.M.., Monday through Friday schedule. Daytime hours shall ensure maximum accessibility.

(G) Narcotic Treatment. The program shall be open to provide treatment seven days per week. Consideration should be given to the employment, homemaking, and educational needs of the clients. Services provided on at least five of these seven days shall be on the basis of an eight-hour day, provided that a minimum of two hours of such eight-hour must be scheduled at a time other than the regular 9:00 A.M. to 5:00 P.M. work-day. Medication dispensing during the remaining two days must be scheduled for a period of at least two hours.

(H) Outpatient Detoxification. The program shall be open to provide treatment seven days per week and, at minimum, four hours per day.

162.401: Admission and Intake

(A) Each licensee shall establish written admission eligibility criteria and shall make such criteria available to prospective clients upon application for admission. A copy of the criteria shall be posted conspicuously in an area frequented by all clients.

(B) If an applicant/client uses medication, prescribed by an outside physician, such use shall not be grounds for denial of admission or for termination from the program, if the medication is approved by the program's Medical Director, who shall not disapprove the medication without having discussed the matter with the prescribing physician. Refusal or failure of the applicant/client to supply the program with written authorization for the Medical Director to discuss medications with prescribing physicians shall constitute legitimate grounds for a program to deny admission or terminate a client from the program.

162.401: continued

(C) Each licensee shall establish a formal intake procedure for potential new admissions and re-admissions and shall include procedures to be followed for alternative referrals, when an applicant is found ineligible for admission. During the intake session, the licensee shall accumulate and record all pertinent client information to effectively evaluate a client's eligibility for the service and his/her service needs. The intake session shall be sufficient to complete the Bureau's MIS form. Verification of physician, psychiatrist, nurse practitioner, physician assistant, or psychologist referral shall be secured by the program within ten days of intake.

(D) Clients who do not meet eligibility requirements or who are inappropriate for the licensee's service shall be referred, where the need exists, to an appropriate service.

(E) Each licensee shall maintain a log of applications of individuals denied admission that shall include: age, race, and sex of applicant; referral source; reason for denial; and referral made.

(F) Admission/Intake Criteria for Specific Programs.

(1) Outpatient Counseling. Verification of a referral from a licensed health care professional, such as a social worker, physician, psychiatrist, psychologist, nurse practitioner, or physician assistant, shall be secured by the program within ten days of intake.

(2) Second Offender Aftercare. Each approved licensee shall provide an initial registration for clients concurrent with their case disposition and assignment to a second offender residential program. Client information may be shared between the probation department, second offender residential program, and the approved licensee in accordance with state and Federal confidentiality laws. If a client's admission to the residential program is more than 28 days following the case disposition, the client shall be admitted to an aftercare counseling service. Admission into an aftercare counseling service shall be within 14 days of case disposition. The client shall remain in aftercare counseling service until which time admission into a Second Offender Residential Program can be achieved. The intake session shall include, when available, the documentation of a clinical diagnoses from the residential program. Clients who do not meet admission eligibility criteria for the licensee shall be referred back to the probation department and the court.

(3) Acupuncture. A written diagnosis or referral, conducted during the previous 12 months by a physician, psychiatrist, Doctor of Osteopathy, dentist, nurse practitioner, or physician assistant, shall be secured by the program prior to the start of treatment pursuant to 243 CMR 5.09(6).

(4) Narcotic Treatment. Prior to admitting a client into treatment, the licensee shall obtain and shall make a part of the client record:

(a) Form FD-2635, "Consent to Treatment with an Approved Narcotic Drug", as required by the FDA, signed by the client. The licensee shall insure that the client signs with full knowledge and understanding of its contents. Where the client is under the age of 18, the consent form shall be signed by the client and the client's parent or guardian.

(b) A client-signed statement, developed by the program which, at a minimum, addresses:

1. distinction between detoxification and maintenance and the availability of short-term detoxification treatment for a period not in excess of 30 days and long-term detoxification treatment for a period more than 30 days but not in excess of 180 days;
2. approximate length of stay in treatment for each program;
3. a clear statement of the goals of each type of treatment; and
4. the options available to both the client and the program as a result of either a voluntary or involuntary termination.

(c) Proof of physiologic narcotic dependence, such proofs may consist of:

1. one or more positive urine tests for opiate or morphine-like drugs;
2. the presence of old and/or fresh needle marks;
3. early physical signs of withdrawal;
4. documented evidence from the medical and personal history;
5. physical examination; and
6. laboratory tests.

(d) Biopsychosocial Examination. Each client shall have a physical examination administered by a program physician or a qualified health-care professional under the supervision of a program physician no later than 14 days after admission.

162.401: continued

1. The physical examination shall rule out infectious disease, pulmonary, liver, and cardiac abnormalities, and dermatologic sequelae of addiction.

2. The physical examination shall include a determination of the client's vital signs (temperature, pulse, blood pressure, and respiratory rate); a medical examination of the head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs, and breasts), abdomen, extremities, skin, and neurological assessment; and the physician's overall impression of the client.

3. Prior to prescribing, dispensing, or administering approved narcotic drugs, the licensee shall ensure that the approved narcotic is not contraindicated with the client's other medications.

4. The psychosocial evaluation shall be performed using an accepted tool approved by the Department.

(e) Laboratory Tests. All laboratories utilized by a narcotic treatment program must comply with all applicable Federal and state licensure and certification requirements. A laboratory work-up shall be performed by qualified personnel no later than 14 days after admission. The laboratory work-up shall include:

1. serological test for syphilis;

2. tuberculin skin test with appropriate referrals, if positive;

3. an initial drug screening urinalysis for opiates, barbiturates, amphetamines, cocaine, methadone, benzodiazepines, propoxyphene, and other drugs, as appropriate, collected in a manner that minimizes falsification;

4. complete blood count and differential;

5. routine and microscopic urinalysis;

6. liver function profile, *e.g*. SGOT, SGBT, *etc.*;

7. Australian Antigen HB Ag Testing (HAA testing);

8. when clinically indicated, an EKG;

9. when clinically indicated, a referral for a chest x-ray or a sickle cell screen;

10. where appropriate, a pregnancy test, a pap smear, and referral for a mammogram; and

11. when clinically indicated, a breathalyzer for alcohol.

(f) The Medical Director shall ensure that:

1. The initial dose of methadone does not exceed the state and Federal dosage guidelines for the specified narcotic, unless opiate abstinence symptoms persist and are documented in the client record and an increased dosage is ordered by the Medical Director; and

2. the initial dose of LAAM to a patient whose tolerance for the drug is unknown does not exceed the Federal regulations and best medical practice for dosing under these conditions.

(5) Outpatient Detoxification. Prior to admitting a client into treatment, the licensee shall obtain and shall make a part of the client record:

(a) a medical evaluation by a licensed physician, psychiatrist, nurse practitioner, or physician assistant which confirms the appropriateness for outpatient detoxification;

(b) within 24 hours of admission, a medical plan of care shall be developed and implemented by a physician assistant, nurse practitioner, or licensed registered nurse;

(c) within 24 hours of admission, an initial drug screening shall be conducted for benzodiazapenes, cocaine, opiates, amphetamines, and other drugs as appropriate, and a breathalyzer to screen for alcohol;

(d) within 48 hours of admission, a physical examination of the client shall be performed by the program physician or a nurse practitioner or a physician assistant under the supervision of a program physician. The physical examination shall:

1. rule out infectious disease, pulmonary, liver, and cardiac abnormalities, and dermatologic sequelae of addiction; and

2. include a determination of the client's vital signs (temperature, pulse, blood pressure, and respiratory rate); a medical examination of the head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs, and breasts), abdomen, extremities, skin, and neurological assessment; and the physician's or a nurse practitioner’s or physician assistant’s overall impression of the client.

162.401: continued

(e) Laboratory Tests. All laboratories employed by a facility must comply with all applicable Federal and state licensure and certification requirements.A laboratory work-up shall be performed by qualified personnel no later than 48 hours after admission. The laboratory work-up shall include:

1. serological test for syphilis;
2. tuberculin skin test with appropriate referrals, if positive;
3. complete blood count and differential;
4. routine and microscopic urinalysis;
5. liver function profile, *e.g.* SGOT, SGBT, *etc.*;
6. Australian Antigen HB Ag Testing (HAA testing);
7. when clinically indicated, an EKG, a chest x-ray, or a sickle cell screen; and
8. where appropriate, a pregnancy test, and referral for a pap smear and a mammogram.

162.402: Orientation

(A) The licensee shall provide a new client with an orientation which will familiarize the client with the rules, procedures, activities, policies, and philosophy of the program.

(B) The licensee shall verbally and in writing inform each client of: program requirements for participation; the nature and goals of the treatment program; the professional staff member(s) who serves as the primary contact with the facility for the client; the cost of the services to be rendered; and disciplinary, termination, and grievance procedures.

(C) The licensee shall deliver to the client at the time of orientation a copy of the Client Policy Manual.

162.403: Evaluation and Diagnosis

(A) The licensee shall be responsible for conducting a complete clinical assessment of each client appropriate to the service required, prior to the development of the individual service plan.

(B) When the initial evaluation indicates a need for further assessment, the licensee shall conduct or make referral arrangements for necessary testing, physical examination, and/or consultation by qualified professionals.

(C) A diagnostic evaluation or assessment must be performed by a Clinician I or a Clinician II. If the evaluation is performed by a Clinician II, it must be reviewed and approved, in writing, by a Clinician I.

(D) Specific Evaluation and Diagnosis Requirements by Program.

(1) Outpatient Counseling. Evaluation and diagnostic services shall be documented in the client record, within the first three visits, but no later than 21 days after admission, and shall include an assessment of the client's psychological, social, health, economic, educational/ vocational, functional, and developmental status; related legal problems; involvement with alcohol and drugs and any other associated conditions. A diagnostic evaluation must be completed before a comprehensive service plan is developed for the client.

(2) Acupuncture. Acupuncture clients shall receive a limited medical screening by a physician assistant, nurse practitioner, or registered nurse, in order to assure that acupuncture treatment for withdrawal is not contraindicated. The screening shall determine: a negative history of seizures, delirium tremens or other life-threatening withdrawal symptoms; neurological evidence of an appropriate level of consciousness; and vital signs. Results of the screening shall be entered into the client record. Clients for whom acupuncture is contraindicated shall be referred and assisted in gaining access to an appropriate level of care.

(3) Second Offender Aftercare. The intake session shall include the documentation of a clinical diagnosis. When possible, this diagnosis may be provided by the residential program. Client information obtained from the residential program and the Office of Probation shall be part of the evaluation.

162.403: continued

(4) Driver Alcohol Education. In addition to the evaluation and diagnosis required in 105 CMR 162.403(A), all clients shall also be assessed. This assessment must include the use of a standardized instrument approved by the Department.

162.405: Individual Service Plan

(A) Each client shall have a written, initial, individual service plan based on clinician\client discussions, and information gathered during the admission and evaluation sessions. Service plans developed or revised by a Clinician III shall be reviewed and signed by a clinical supervisor.

(B) The service plan and any subsequent updates shall include at least the following information:

(1) a statement of the client's problem in relation to misuse of alcohol and drugs expressed in behavioral terms;
(2) a statement of the client's strengths and skills;
(3) service goals expressed in behavioral terms with time lines for achieving these goals;
(4) evidence of client involvement in formulation of the service plan;
(5) clearly defined staff responsibilities and assignments for implementing the plan;
(6) the date the plan was developed and/or revised and anticipated duration of treatment;
(7) the signatures of staff and client involved in its formulation or review;
(8) when indicated, an aftercare plan;
(9) prescription medication, prescribed dosage(s) of all medications, plans for changing prescribed medications, including the planned rate of detoxification, when applicable;
(10) for narcotic treatment programs, documentation of treatment options for the client to reach his/her highest level of functioning and documentation, justification, and evaluation of dosages every 90 days; and
(11) documentation of disability, if any, which requires a modification of policies, practices, or procedures and record of any modifications made.

(C) Service plans shall be reviewed every 90 days.

(D) The staff responsible for implementing the plan shall review the service previously prescribed for the client and determine the future course of service which shall be described in a service plan update. If the counselor is a Clinician III, the service plan update shall be approved by a clinical supervisor.

(E) Service plans for clients receiving driver alcohol education services shall be reviewed at mid-point in the group educational programming.

162.406: Treatment

(A) Treatment shall be provided to clients with sufficient frequency so as to maintain a continuity of treatment appropriate to the needs of the client.

(B) Counseling sessions shall focus on the alcohol and other drug abuse and any related personal, family, or job/school problems.

(C) Counseling services offered shall include individual, group, couple, and family therapy. Ongoing psychodynamic groups shall include a maximum of ten clients. Ongoing psychoeducational groups shall include a maximum of 15 clients.

(D) The licensee shall provide case management which shall, at a minimum, include:

(1) crisis referrals;
(2) health care referrals;
(3) continuum of care referrals;
(4) vocational and/or educational referrals;
(5) aftercare referrals;
(6) follow-up services;
(7) legal services referrals; and

(8) housing referrals.

(E) Case consultation with other client-care givers or institutions, *e.g.* courts, schools, Department of Youth Services, Department of Social Services, *etc*., shall be provided as needed and recorded in the client's record.

(F) The licensee shall provide HIV/AIDS education to all clients admitted to the service, and annually thereafter. HIV/AIDS education shall be provided by a trained HIV/AIDS educator, documented in the client record, and shall conform to policies set forth by the Department. HIV/AIDS education shall include, but need not be limited to, the following:

(1) the etiology and transmission of HIV infection and associated risk behaviors;
(2) symptomatology and clinical progression of HIV infection and AIDS;
(3) prevention of transmission or risk reduction;
(4) the purpose, uses, and meaning of available testing and test results;
(5) confidentiality issues; and
(6) the interaction between alcohol and other drug use and its effect on the immune system and the progression of AIDS.

(G) Pharmacological services shall be provided as needed by staff physicians, nurse practitioners, or physician assistants or by affiliation with another facility.

(H) Treatment Requirements for Specific Programs.

(1) Acupuncture. Acupuncture treatment shall, at a minimum, consist of:
(a) intensive acupuncture administration (six treatments per week) for detoxification purposes and several months of less intensive treatment (two to three times per week) for maintenance;
(b) a primary counselor who shall be assigned to provide case management and motivational counseling which shall focus on engaging the client to remain in acupuncture treatment;
(c) supportive counseling during the maintenance phase which shall motivate the client to begin the transition into ongoing substance abuse outpatient treatment and self help groups. Supportive counseling sessions shall include HIV risk assessment and AIDS education; and
(d) outreach services to attract underserved target populations, maintain client census, and develop linkages with community agencies.

(2) Intensive Outpatient. Intensive outpatient treatment shall, at a minimum, consist of:
(a) group counseling offered a minimum of three days per week,
(b) counseling sessions which shall focus upon:
1. effects of substance abuse;
2. for specialized services for pregnant and parenting women, necessity and importance of prenatal care and parenting skills;
3. relapse prevention; and
4. communicable diseases prevention, including AIDS education and risk reduction;
(c) individual and/or family counseling;
(d) case management; and
(e) encouragement of the use of self-help groups by program participants.

(3) Day Treatment. Day treatment shall provide each client with a minimum of:
(a) four hours of counseling three days per week with topics as outlined in 105 CMR 162.406(H)(2)(b) and, in addition, topics that address skill-building in self management and self care;
(b) individual and/or family counseling; and
(c) case management that encourages the use of self-help groups by program participants.

(4) Second Offender Aftercare. Second offender aftercare shall be provided coterminous with the client's probation period and shall include the following:
(a) completion of the following three-phase program: Phase One - a two-week inpatient residential program pursuant to M.G.L. c. 90, § 24; Phase Two - no less than eight individual or group assessment sessions; and Phase Three - additional counseling to be determined in accordance with the individual service plan.

(b) counseling services that emphasize the cessation of alcohol and other drug use and driving;

(c) the administration of breathalyzer tests no less than every 90 days to evaluate client compliance with his/her individual service plan;

(d) the analysis of one random urine for drugs of abuse during the aftercare program; and

(e) the filing of regular reports with the office of probation detailing the client's status, including a complete evaluation of the client's compliance with the client's service plan 30 days prior to the end of probation.

(5) Driver Alcohol Education. The licensee approved to provide driver alcohol education shall provide 40 hours of treatment service over a period of 16 to 20 weeks, including assessment and group education programming approved by the Department that shall consist of the following:

(a) group education sessions that focus on the client's problem drinking habits and the dangers of drinking and driving and that assist clients in developing and achieving appropriate alcohol use. Such groups shall be interactive and include a maximum of 15 clients;

(b) special programming for the under-21 offender, which addresses issues pertinent to youth;

(c) special programming or referrals to other programs for linguistic/cultural need, employment/child care conflicts, and mental health issues; and

(d) referrals back to the court of any client who the licensee deems inappropriate for the service.

(6) Narcotic Treatment. Narcotic treatment, in addition to providing medication and evaluation, shall provide, at a minimum, counseling, rehabilitation, and other social services, including vocational, educational, and employment guidance which will help the client become a well functioning member of society.

(a) The licensee shall operate in accordance with:

1. M.G.L. c. 94C and 105 CMR 700 *et seq.*;
2. the rules and regulations of the FDA;
3. the rules and regulations of the Drug Enforcement Administration (DEA); and
4. the rules and regulations of the Department.

(b) The Medical Director, or any other authorized staff physician, shall be responsible for the following minimal requirements:

1. ensuring that evidence of current physiological dependence is recorded in the client record;
2. ensuring that a medical evaluation, including a medical history, has been taken;
3. ensuring that appropriate laboratory studies have been performed;
4. signing or countersigning all medical orders; and
5. reviewing and countersigning treatment plans at least annually. The annual review shall document in the client record the justification for, or contraindication thereof, continued maintenance and any justification for the therapeutic use of take-home medication.

(c) The licensee shall have a photograph identification system for identifying clients when dispensing chemotherapeutic substances.

(d) The licensee shall report within 14 days of occurrence to the FDA on Form-1639 a detailed account of any adverse physical or psychological reactions.

(e) Clients shall be stabilized at their optimal dosage levels before they may be referred to a medication unit.

(f) The program sponsor shall ensure that a client referred to a medication unit receives needed medical and rehabilitative services at the primary facility.

(g) The program sponsor and Medical Director shall determine that the client to be referred to a medication unit is not in need of frequent counseling, rehabilitative, and other services which are only available at the primary program facility.

(I) Narcotic Detoxification.

(1) A program physician shall determine, separately for each client, the rate at which the narcotic drug is to be decreased. Clients who are being detoxified as a planned goal in a maintenance program may enter into an agreement with the program for a blind detoxification. Such agreement shall be renewed only by mutual consent on a regular basis.

162.406: continued

(2) A waiting period of at least one week shall be required between detoxification attempts. Any authorized staff physician shall document in the client record that the client continues to be or is again physiologically dependent on a narcotic drug.

(3) All requirements for maintenance treatment apply to detoxification treatment with the following considerations:

(a) a history of one year physiologic dependence is not required for admission;

(b) clients who have been determined by the program physician to be currently physiologically narcotic-dependent may be detoxified with narcotics, regardless of age;

(c) only the initial drug screening urinalysis and one additional random test need be performed monthly;

(d) periodic treatment plan evaluations are required monthly; and

(e) the requirements of 21 CFR 291.505(d)(6): *Federal Treatment Standards* [except (d)(6)(ii)(a) through (d)(iii) and (iv)] do not apply to detoxification treatment.

(4) The licensee shall dispense narcotics daily at the facility under the direct supervision of a physician or other qualified medical person.

(5) The licensee shall not provide take home-medication.

(J) Narcotic Maintenance Treatment.

(1) No applicant shall be admitted unless he/she is currently physiologically dependent upon a narcotic drug and has at least a documented history of opiate dependency beginning one year prior to application for treatment. In the case of a person for whom the exact date on which physiological addiction began cannot be ascertained, the admitting physician may, in his/her reasonable clinical judgment, admit the person to narcotic maintenance treatment, if from the evidence presented, observed, and recorded in the client record it is reasonable to conclude that there was physiologic dependence at a time approximately one year prior to admission.

(2) Urine Testing.

(a) An initial drug-screening shall be completed for each prospective client.

(b) At least two additional random, supervised urinalysis for methadone, opiates, cocaine, benzodiazepines, barbiturates, and propoxyphene shall be performed on each client each month in treatment.

(c) Results of urine testing shall be used as a clinical tool and not as the sole factor in the diagnosis and treatment of the client and for monitoring the client's drug-use patterns before and during treatment. The licensee's Medical Director shall ensure that urine test results are not used to force a client out of treatment, but are used as an aid in making treatment decisions.

(d) Drug screening may be done by urine testing, but no client with a medically confirmed disability which inhibits him/her giving urine on demand should be required to do so, and the licensee shall screen for drug use by other effective means which reasonably accommodate the client's disability. Such medical disabilities must be confirmed by the program's Medical Director.

(e) Any client with clean urine screens for a period of 24 consecutive tests may request in writing from the licensee the use of unsupervised urine screens with random supervision until which time the program revokes this privilege for documented cause, at their discretion.

(3) A person under 18 years of age shall not be admitted to LAAM maintenance treatment.

(4) The Medical Director shall ensure that the initial dose of LAAM for a previously stabilized methadone maintenance client not exceed the state and Federal dosage guidelines or best medical practice guidelines for the specified narcotic

(5) The administering physician shall ensure that a single dose of LAAM greater than 140 milligrams is justified in the client's record.

(6) After a client's tolerance to LAAM is established, LAAM shall not be administered more frequently than Federal law and best medical practices warrant.

(7) Administration of Narcotics.

(a) With the exceptions listed below, all clients who begin methadone maintenance treatment shall present themselves daily for medication so that the licensee may observe the client ingesting the prescribed dosage of methadone on a daily basis.

(b) After at least three months of methadone maintenance treatment and after showing substantial progress in rehabilitation, a client may be permitted to reduce to three times per week the number of times when they must ingest the methadone under observation. The licensee shall dispense no more than a two-day take-home supply to the client. The licensee shall document the reasons for authorizing methadone take-home privileges in the client record.

(c) After at least two years of maintenance treatment and where rehabilitative progress would be enhanced by decreasing the frequency of client attendance, the client may be permitted to reduce to twice weekly the number of times he/she must ingest the methadone under observation. The licensee shall dispense no more than a three-day take-home supply.

(d) The requirements for when methadone must be ingested under observation may be relaxed temporarily or permanently if, in the reasonable clinical judgment of the program physician, the client has a mental or physical disability. An individual, authorized by the licensee, shall deliver the narcotic to the client. The authorized individual may be any person who has demonstrated the ability and willingness to responsibly deliver doses to the client. The FDA shall approve, and the Department be notified of such cases. The reasons for take-home privileges, or contraindications for, shall be documented in the client record.

(e) In exceptional circumstances, the Medical Director may dispense additional methadone for a specific period where client hardship would result from requiring the customary methadone intake. The licensee shall record the reasons for providing additional methadone in the client record.

(f) In exceptional circumstances, such as severe illness, personal or family crises, travel, or other hardship, the client may be permitted a temporarily reduced attendance schedule, provided he/she is also found to be responsible in handling narcotic drugs. The FDA shall approve, and the Department be notified of such cases. The reasons for this exception shall be entered in the client record.

(g) A client may not be given more than a two-week supply of methadone at one time.

(h) Take-home privileges may be revoked or suspended if the client does not maintain those behavior changes which allowed take-out privileges in the first place.

(i) A pregnancy test is required for any woman of childbearing potential before she may be administered LAAM. Pregnancy tests shall be preformed monthly thereafter by state-approved laboratories.

(j) Take-home doses of LAAM are not permitted.

(k) The rate of detoxification shall be determined by the program's Medical Director. Except as provided under 105 CMR 162.407(E)(1), dose reductions shall be less than 20% of the client's established tolerance or maintenance dose; and there shall be three day intervals between dose reductions, not to exceed 5 mg. per day, except when requested in writing by the client and approved by the Medical Director.

(8) Pregnant Women.

(a) Pregnant clients, regardless of age, who have had a documented narcotic dependency in the past and who may be in direct jeopardy of returning to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a maintenance regimen. For such clients, evidence of current physiological dependence on narcotic drugs is not needed if the Medical Director, or any other authorized staff physician, certifies the pregnancy and, in his/her reasonable clinical judgment, finds such treatment to be medically justified in accordance with best medical practices considering the health of the mother and impact on the pregnancy. Evidence of all findings shall be recorded in the client record.

(b) The licensee shall take caution in the maintenance of pregnant women. Dosage levels shall be maintained as low as possible, if continued methadone maintenance is deemed necessary. It is the responsibility of the licensee to ensure that each pregnant client is fully informed concerning the possible risks to herself and to her unborn child.

(c) The licensee shall make referral arrangements for the provision of pre-natal and delivery services.

(d) Clients who are or become pregnant shall not be started or continued on LAAM. Programs providing treatment with LAAM must document that they advise all women of childbearing potential of the risks of LAAM and make a medical evaluation available to all clients who become pregnant while taking the drug.

162.406: continued

(9) Termination.

(a) Upon successfully reaching a drug-free state, the client shall be offered services from the program as long as necessary to assure stability.

(b) Upon the request of the client or where appropriate, the licensee shall make arrangements for an immediate transfer to another facility, if possible. Where transfer is not possible, other arrangements for detoxification shall be made.

(K) Current affiliation agreements for emergency inpatient medical and emergency inpatient psychiatric services shall be secured by the licensee, regardless of the client's ability to pay.

162.407: Termination and Aftercare

(A) Each licensee shall establish and maintain written procedures detailing the termination process and shall incorporate them into the policy manual. These procedures shall include written criteria for termination, defining:

(1) successful completion of program;
(2) voluntary termination prior to program completion;
(3) involuntary termination;
(4) medical discharge; and
(5) transfers and referrals.

(B) Upon each termination the counselor shall prepare, and include in the client record, a written discharge summary and aftercare plan. The aftercare plan shall include ongoing services and client goals and objectives following discharge.

(C) The discharge summary shall contain, but need not be limited to:

(1) description of the treatment episode,including length and description of treatment;
(2) sobriety status and a description of current drug and alcohol use;
(3) vocational/educational/financial status;
(4) related legal problems;
(5) reason for termination;
(6) referrals; and
(7) follow-up plans.

(D) Rules of required conduct and procedures for involuntary terminations shall not prevent or interfere with a client's voluntary termination from treatment with detoxification planned by mutual consent.

(E) Procedures for involuntary terminations from a narcotic treatment program:

(1) In an emergency situation, the licensee may suspend a client immediately and without provision for detoxification when the program director reasonably determines that the client's continuance in the program presents an immediate and substantial threat of physical harm to other clients or program personnel or property; or where the program's Medical Director reasonably determines that continued treatment of a client presents a serious documented medical risk. Thereafter, the client shall be afforded a review, including the opportunity to be heard at a hearing no later than seven days from the client's receipt of the written notice of suspension, as provided in 105 CMR 162.407(E)(2).

(2) In a non-emergency situation, where the client's continuance does not present the immediate and substantial threat of harm or serious medical risk described in 105 CMR 162.407(E)(1), the licensee may not terminate, suspend, or commence any involuntary detoxification on the client without first affording him/her the following procedural rights:

(a) prompt written notice which shall contain:

1. a statement of the reasons for the proposed termination, *e.g*. violations of a specific rule or rules, non-compliance with treatment contract, *etc*., and the particulars of the infraction including the date, time, and place;

2. notification that the client has the right, within two working days of the receipt of written notice, to submit a written request for a hearing as to the proposed termination;

162.407: continued

3. the program and the client or his/her advocate shall then arrange for a mutually convenient date and time for a hearing within ten working days thereafter;

4. additional time to secure appropriate representation may be granted under exceptional circumstances; and

5. a copy of the licensee's hearing procedures.

(b) an opportunity to be heard at a hearing in accordance with the procedures specified hereafter:

1. The hearing shall be presided over by an impartial hearing officer of officers who may be any staff or other person(s) not directly involved in the facts of the incident giving rise to the disciplinary proceedings or in the decision to commence the proceedings; provided that the persons involved in either the facts of the incident or in the decision to commence the proceeding shall not have authority over the hearing officer(s);

2. The client may be represented at the hearing by any responsible adult of the client's choosing, including legal counsel;

3. The hearing shall be conducted in accordance with previously established written rules which need not be the rules of evidence used in judicial proceedings, but which shall be designed to ensure a fair and impartial proceeding, provided that the program shall prove by a preponderance of the evidence that a client did commit the alleged violation;

4. The client shall be entitled, upon request, to examine any documentary evidence in the possession of the licensee which pertains to the subject matter of the hearing;

5. The client shall be entitled to call his/her own witness and to question any adverse witness;

6. The client and/or licensee shall record the hearing by any means of his/her own choosing and at his/her own expense, provided that the means of recording does not substantially interfere with the proceedings;

7. The hearing officer will make his/her decision within seven days after the hearing and will base the decision solely upon the information presented at the hearing. The decision shall also be based upon clinic rules and regulations that were in effect at the time of the violation and had previously been posted.

8. The hearing officer shall provide the client with his/her decision in writing shall include an explanation of the reasons for the decision, and shall provide the client (and his/her representative, if requested) with a copy thereof. The written decision shall include instructions to the client explaining how to file an appeal of an adverse decision to the Bureau.

162.408: Bureau Review of Program Disciplinary Actions

(A) The licensee shall afford the client an appeal of an adverse decision of the hearing officer to the Bureau. The client must request this appeal in writing to the Bureau within three working days of the receipt of the adverse decision. A brief written argument in support of the appeal must be provided to the Bureau within an additional three working days. The Bureau will either affirm or reverse the hearing officer's decision, or remand the decision to a new hearing officer for a new hearing. The decision of the Bureau will be made within ten days of the Bureau’s receipt of the complete record and written materials submitted by both parties. A licensee’s failure to submit the complete record will result in a finding for the client. The hearing officer shall deliver a written decision, outlining the reason(s) for the decision, to the client, his/her advocate, and the program.

(B) The licensee may not terminate, suspend, or impose any lesser sanction on the client without first receiving, and insuring that the client also receives, the decision on appeal.

(C) Clients in a narcotic treatment program, if terminated or suspended in accordance with 105 CMR 162.407(E)(2), shall, and if terminated or suspended in accordance with 105 CMR 162.407(E)(1), may, at the licensee's discretion, be afforded the opportunity of detoxification. The licensee shall either itself detoxify the client or make arrangements for appropriate detoxification in another narcotic treatment program.

162.408: continued

(D) The rate of detoxification shall be determined by the program's Medical Director to be appropriate to the client's medical condition and the dosage level at which the client was being medicated before the final decision was made to terminate or suspend. In determining an appropriate course of detoxification, the Medical Director shall examine the client, review his/her record, consider his/her physicial and mental health status, and, upon request of the client, may take into account the opinions of the client's other physicians and medical providers.

162.500: Additional Requirements for Narcotic Treatment Programs

(A) State Authority Approval.

(1) Request for State Authority Approval. Before a narcotic treatment program may be lawfully operated, the program must receive State Authority approval of its application to operate a narcotic treatment program and FDA approval of its application. The Bureau shall not process the State Authority approval until the applicant has satisfied all Bureau licensure requirements. Narcotic treatment programs operated by the Veterans Administration and programs directly operated by the Federal government do not need to obtain State Authority approval. Any applicant seeking to establish or operate a narcotic treatment program, or expand an existing narcotic treatment program to a new site, satellite, or medication unit, shall submit to the State Authority:

(a) a Request for State Authority Approval to Operate a Narcotic Treatment Program (or "application");

(b) a standard Bureau application for licensure to operate substance abuse outpatient services in accordance with 105 CMR 162.100;

(c) copies of the applications to the Federal Food and Drug Administration; and

(d) copies of the applications to the Federal Drug Enforcement Administration.

(2) Community Siting Process. Prior to the submission of a new application to operate a narcotic treatment program, or change location, the applicant shall complete a process requiring community input and shall submit a summary of this process and comments to the Bureau. The required Community Process shall include, but not be limited to:

1. name and address of the applicant;
2. location and description of the service to be provided;
3. proposed date of formal application; and
4. input from interested parties which shall include, but is not limited to: elected head of the political subdivisions, mayor, city manager, legislator(s), other elected and appointed officials, Chief of Police, abutters of property at the proposed site, community leaders, and recognized community organizations.

(3) Application for State Authority Approval to Operate a Narcotic Treatment Program.

(a) The applicant shall submit a completed "Request for State Authority Approval to Operate a Narcotic Treatment Program," in addition to submission of an application for licensure pursuant to 105 CMR 162.100 and 101, on Department forms which shall include at a minimum the following information:

1. estimated start-up date;
2. description of need;
3. description of services to be provided;
4. Community Siting Process report;
5. affiliation agreement(s) specific to the medication unit;
6. identification of outpatient services provider, if not the applicant;
7. the number of active clients to be served at the site(s); and
8. security protocols.

(4) State Authority Approval or Denial for Narcotic Treatment Program .

(a) The Bureau shall not process State Authority approval until the applicant has satisfied all Bureau licensure requirements. Once the applicant demonstrates that state licensure requirements are met, the Bureau shall conduct a review of all state and Federal forms prior to responding to FDA requests for recommendations of approval and shall withhold any State Authority approvals if it has not had an opportunity to review the state and Federal applications prior to the request for Federal approval.

(b) The Bureau shall evaluate the application and review the following factors: need, community support, and program operations to determine whether the interests of public health would be served by the establishment of the narcotic treatment program at the proposed site.

162.500: continued

(c) If the Bureau determines that the applicant has met all state and Federal standards and that the interests of public health would be served by the establishment of the narcotic treatment program, the Bureau shall forward State Authority approval to the FDA.

(d) Upon State Authority approval, the Bureau shall issue a provisional license valid for six months and shall sign and forward to the FDA the FDA form with Department approval.

(e) The Bureau may review the program's operations during the provisional licensing period. Following the provisional period, the Bureau shall make a recommendation to the Public Health Council regarding issuance of a two year license.

(f) If the Bureau determines that the applicant has not met the requirements of state and Federal regulations and/or that the interests of public health would not be served by the establishment of the narcotic treatment program at the proposed site, the Bureau shall deny State Authority approval of the application in writing, citing specific reasons for denial, and forward its denial to the FDA. If denied, the applicant may request an adjudicatory hearing, pursuant to M.G.L. c. 30A and 801 CMR 1.01(7). In addition, a narcotic treatment program may appeal to the FDA a denial or revocation of approval by the State Authority, unless the denial or revocation is based upon a State law or regulation 21 CFR 291.505(h)(5).

(g) The State Authority may make a request to FDA to revoke FDA approval of a narcotic treatment program for cause.

(5) Inspections of Narcotic Treatment Program.

(a) A program shall allow inspections by duly authorized employees of the State Authority, the FDA, DEA, and NIDA at any time.

(b) A hospital shall permit the State Authority and FDA to inspect supplies of narcotic drugs for narcotic addiction treatment which are located at the hospital at any time and to evaluate the uses to which the drug(s) are being put. In addition, records on receipt, storage, and distribution of narcotic medication are subject to inspection.

(6) State Authority Approval of Hospital Pharmacy. The State Authority must approve the application for a hospital pharmacy to provide narcotic drugs for detoxification treatment.

(7) Notification Requirements.

(a) Change in program sponsor or Medical Director. The narcotics treatment program must provide written notice to the State Authority of a replacement of a program sponsor or Medical Director within three weeks of any replacement of these personnel.

(b) Closure or Cessation of Operation. The narcotics treatment program must provide written notice to the State Authority three weeks in advance of discontinuing a program in which medication is administered or dispensed.

REGULATORY AUTHORITY

105 CMR 162.000: M.G.L. c. 111B, § 6B; c. 111E, § 7 and c. 90, §§ 24 and 24D.

NON-TEXT PAGE